

PTC/SB-08-08-05

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## INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(type as many shots as necessary)

Sheet 1 of 1

<b>Application Number</b>	09/430,966
<b>Filing Date</b>	11/01/1999
<b>First Named Inventor</b>	Bart DE CORTE
<b>Group Art Unit</b>	1624
<b>Examiner Name</b>	VENKATARAMAN BALASUBRAMANIAN
<b>Attorney Docket Number</b>	JAB 1425

## OTHER - NON PATENT LITERATURE DOCUMENTS

OTHER - NON PATENT LITERATURE DOCUMENTS					
Examiner's initials*	Cite No. <sup>†</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	Translation	T <sup>a</sup>	
m		VINGERHOETS, Antiviral activity TMC 125 SDM, CROI, San Francisco, Feb. 2004	No		
		ARNOLD, Conformational Flexibility of DAPYs: activity against resistant HIV, Aug. 2003	No		
		VINGERHOETS, Resistance before/after therapy - TMC 125C207, XII Resistance Mexico, June 2003	No		
		VINGERHOETS, Resistance profile clinical isolates TMC 125, XII Resistance Mexico, June 2003	No		
		GAZZARD, TMC 125 C207 study treatment-experienced, CROI Seattle, Feb. 2002	No		
		LANGE, TMC 125 decay rate vs ERA, CROI Seattle, Feb. 2002	No		
		GAZZARD, 7 day treatment-experienced, WAC Barcelona, Jul. 2002	No		
		LEWIS, Potency & multiple binding modes of TMC 125, CROI Boston, Feb. 2003	No		
		M-P de BETHUNE, TMC 125 resistance profiles, Resistance, Mexico, June 2003	No		
		VINGERHOETS, TMC 125-C207 resistance analysis, Resistance, Mexico, June 2003	No		
		TMC 125 for 7 days in HIV-1+ Individuals with NNRTI resistance (TMC 125-C207), AIDS, 17(18): F49-S4, Dec. 5, 2003	No		
		TMC 125 as 7d monotherapy in ARV-naïve subjects (TMC 125-C208), AIDS, 17(17): 2487-2494, Nov. 21, 2003	No		
		TMC 125 similar potency to 5-drug, 3-class regimen, AIDS, 17(18): 2623-2627 Dec. 5, 2003	No		
		UDIER-BLAGOVIC, Validation of a model for the complex of HIV-1 reverse transcriptase with nonnucleoside inhibitor TMC125, Journal of American Chemical Society, 2003, 125(20), pp.6016-6017	No		
		GULICK, New Antiretroviral drugs, Clinical Microbiology and Infection, 2003, 9(3), pp.186-193	No		
m		LUDOVICI, Evolution of anti-HIV drug candidates. Part 3: diarylpyrimidines, (DAPY) analogues. Bioorganic & Medicinal Chemistry Letters (2001), 11(17), pp. 2235-2239.	No		

Examiner Signature	V. Balasubramaniam	Date Considered	7/29/06
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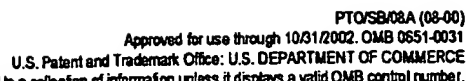
<b>Substitute for form 1449A/PTO</b>  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (use as many sheets as necessary) <b>Sheet 2 of 3</b>	<b>Application Number</b>	09/430,966
	<b>Filing Date</b>	11/01/1999
	<b>First Named Inventor</b>	Bart De Corte
	<b>Group Art Unit</b>	1614
	<b>Examiner Name</b>	V. Balasubramanian
	<b>Attorney Docket Number</b>	JAB 1425

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VM	2	GRUZDEV, et al., <i>A Randomized, double-blind, placebo-controlled trial of TMC125 as 7-day monotherapy in antiretroviral naïve HIV-1 infected subjects</i> , AIDS 2003, VOL 17, pp. 2487-2494.	No	
	3	SANKATSING, et al., <i>TMC125 exerts similar initial antiviral potency as a five-drug, triple class antiretroviral regimen</i> , AIDS 2003, Vol. 17, pp. 2623-2627.		
	4	GAZZARD, et al., <i>An open-label assessment of TMC 125 - a new, next-generation NNRTI, for 7 days in HIV-1 infected individuals with NNRTI resistance</i> , AIDS 2003, Vol. 17, pp. 49-54.		
	5	LUDOVICI, et al., <i>Evolution of Anti-HIV Drug Candidates. Part 3: Diarylpyrimidine (DAPY) Analogues</i> , Bioorganic & Medical Chemistry Letters 11, 2001, pp. 2235-2239.		
	6	UDIER-BLAGOVIĆ, et al., <i>Validation of a Model for the Complex of HIV-1 Reverse Transcriptase with Nonnucleoside Inhibitor TMC125</i> , J. AM. CHEM. SOC. 2003, Vol. 125, pp. 6016-6017.		
	7	GULICK, <i>New Antiretroviral Drugs</i> , Clinical Microbiology and Infectious Diseases, CMI, 9, (3) pp. 188-193 (March, 2003)		
	8	FURUKAWA, et al., <i>Syntheses of Compounds related to Guanidine and their Inhibitory Action on Growth of HeLa Cells</i> , Chem. Pharm. Bull. 9 (11), 914-921 (1951)		
	9	GAZZARD, et al., <i>TMC125, A Next-Generation NNRTI, Demonstrates High Potency After 7 Days Therapy in Treatment-Experienced HIV-1 Infected Individuals with Phenotypic NNRTI</i> , CROI, Seattle, Feb. 2002.		
	10	VINGERHOETS, et al., <i>Antiviral activity of TMC125, a potent next-generation NNRTI, against &gt; 5000 recombinant clinical isolates exhibiting a wide range of (NNRTI) resistance</i> , XIIIth International HIV Drug Resistance Workshop, June 10-14, 2003, Mexico.		
	11	VINGERHOETS, et al., <i>Characterization of Resistance Before and After Short-Term Therapy with TMC125 in Patients with Documented NNRTI Resistance</i> , XIIIth International HIV Drug Resistance Workshop, June 10-14, 2003, Mexico		
	12	GAZZARD, et al., <i>TMC125, a Next Generation NNRTI, Demonstrates High Potency After 7 Days Therapy in Treatment-Experienced HIV-1 Infected Individuals with Phenotypic NNRTI-Resistance</i> , XIV International AIDS Conference, July 2002, Barcelona, Spain		
	13	SANKATSING, et al., <i>TMC 125 Monotherapy for One Week Results in a Similar Initial Rate of Decline of HIV-1 RNA as Therapy With a 5-Drug Regimen</i> , CROI, Seattle, Feb., 2002.		
MB	14	ARNOLD, et al., <i>Inhibitor conformational flexibility and positional variation are important for activity against drug-resistant virus: crystal structures of highly potent non-nucleoside inhibitors of HIV-1 reverse transcriptase</i> , 21 <sup>st</sup> European Crystallographic Meeting, Durban, South Africa, 24-29, Aug. 2003.		

Examiner Signature	V. Balasubramanian	Date Considered	7/29/04
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\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. 1 Applicant's unique citation designation number (optional). 2 See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. 3 Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). 4. For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. 5 Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. 6 Applicant is to place a check mark here if English language Translation is attached.  
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**Sheet 3 of 3**

<b>Application Number</b>	09/430,966
<b>Filing Date</b>	11/01/1999
<b>First Named Inventor</b>	Bart De Corte
<b>Group Art Unit</b>	1614
<b>Examiner Name</b>	V. Balasubramanian
<b>Attorney Docket Number</b>	JAB 1425

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[illegible]

Examiner Signature	V. Balasubraman	Date Considered	7/29/04
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<b>Substitute for form 1449A/PTO</b>  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (use as many sheets as necessary) <b>Sheet 1 of 1</b>	<b>Application Number</b>	09/430,966
	<b>Filing Date</b>	11/01/1999
	<b>First Named Inventor</b>	Bart De Corte
	<b>Group Art Unit</b>	1614
	<b>Examiner Name</b>	V. Balasubramanian
	<b>Attorney Docket Number</b>	JAB 1425

**U.S. PATENT DOCUMENTS**

Examiner Initials	Cite No. <sup>1</sup>	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document mm-dd-yyyy	Misc.
		Kind Code <sup>2</sup> (if known)	Number			

**FOREIGN PATENT DOCUMENTS**

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		Office <sup>4</sup>	Number <sup>4</sup>	Kind Code <sup>5</sup>				

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W	1	J. VINGERHOETS et al., Antiviral Activity of TMC Against a Panel of Site-Directed Mutants Encompassing Mutations Observed <i>In Vitro</i> and <i>In Vivo</i> , Poster No. 621, Presented at the Xth Conference on Retrovirus and Opportunistic Infections, Feb 8-11, 2004, San Francisco, CA, USA	No	

Examiner Signature	V. Balasubramanian	Date Considered	7/29/04
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Sheet 1 of 1

Application Number	09/430,966
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First Named Inventor	Bart De Corte
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		Office <sup>3</sup>	Number <sup>4</sup>	Kind Code <sup>5</sup>				
W	1	EP	0135472	A2	CIBA-GEIGY A.G.	03-27-1985	English Abstract	

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		Office <sup>3</sup>	Number <sup>4</sup>	Kind Code <sup>5</sup>				
WD	1	EP	0588762	A1	CIBA-GEIGY A.G.	03-23-1994	Yes	

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